

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty Docket No. 046714/0113

In re: U.S. Patent No. 5,362,755
Patentee: Timothy J. BARBERICH et al.
Assignee: Sepracor, Inc.
Issue Date: November 8, 1994

STATUS INQUIRY

Commissioner for Patents and Trademarks
Washington, D.C. 20231

FAX RECEIVED**APR 01 2003****PETITIONS OFFICE**

Applicants respectfully inquire as to the status of the above-referenced patent term extension. The patent has an issue date of November 8, 1994. A Request for Extension of Patent Term Under 35 U.S.C. §156 was filed May 21, 1999. The last known communication regarding this patent was a letter dated December 30, 2002 (copy attached), to The Honorable James E. Rogan, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office from Jane A. Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, Food and Drug Administration. To date, no further communication has been received on this application.

Respectfully submitted,

Date

April 1, 2003

By

Stephen B. Maebius

FOLEY & LARDNER,

Customer Number: 22428

**22428**

PATENT TRADEMARK OFFICE

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<p>From: Diana Meinecke Legal Assistant to Stephen B. Maebius</p> <p>Sender's Direct Dial: 202-945-6135</p> <p>Date: April 1, 2003</p>
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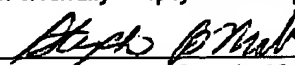
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PETITIONS OFFICE

MESSAGE:

U. S. Patent No. 5,362,755
Sepracor, Inc.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 19-0741 in reference to the required Amendment fee.


Stephen B. Maebius, Reg. No. 35,264

CERTIFICATION

I hereby certify that this document is being facsimile transmitted to U.S. Patent and Trademark Office, Attn: Karin Ferriter, Office of Petitions, on the date shown below, (1) Status Inquiry.

4/1/03
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Diana H. Meinecke

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NO. 022

D02



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857Re: Xoponex
Docket No. 99E-5116

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

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This is in regard to the application for patent term extension for U.S. Patent No. 5,362,755 filed by Sepracor, Inc., under 35 U.S.C. § 156. The human drug product claimed by the patent is Xoponex (levabuterol), which was assigned new drug application (NDA) No. 20-837.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F.2d 392 (Fed. Cir. 1990).

The NDA was approved on March 25, 1999, which makes the submission of the patent term extension application on May 21, 1999, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Harold C. Wegner
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